UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte FRIEDEL FRAUENDORFER

Appeal No. 2006-0271
Application No. 09/719,258

ON BRIEF

Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-14, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. An oral dosage form for food, food supplements and dietetics comprising polyunsaturated fatty acids in a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids.

The references relied upon by the examiner are:

Yajima et al. (Yajima)	4,525,306	Jun. 25, 1985
Buser et al. (Buser)	5,948,818	Sep. 7, 1999
Fischer[1]	EP 0240581	Oct. 14, 1987
Akikuni et al. (Akikuni)[2]	JP 09-000201	Jan. 7, 1997
Cade et al. (Cade)	WO 97/04755	Feb. 13, 1997

GROUNDS OF REJECTION

I. Claims 1-9 and 11-14[3] stand rejected under 35 U.S.C. § 103, as being unpatentable over the combination of Cade and Akikuni.

II. Claims 1-5, 7, and 9-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Yajima and Cade.

III. Claims 1-5 and 12-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Fischer and Buser.

We affirm rejection III. We reverse rejections I and II.

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[1] We note that this document is incorrectly identified in the Answer and Supplemental Answer as Flacher. This typographical error may be due to the examiner's reliance on the October 1, 2004, translation of this document, which identifies the inventor as Flacher. However, upon consideration of the original document entered into the record on August 12, 2003, we find that the name of the inventor is Fischer.

[2] We note that appellant refers to this reference as "XP-002143507" or "XP". Brief, page 4. For his part, the examiner refers to this reference as "JP 09-000201" or "JP '201". Supplemental Answer, page 3.

[3] We note that claim 5 was not included in this rejection in the Final Office Action, mailed October 29, 2003, page 2.

DISCUSSION

The combination of Cade and Akikuni:

Claims 1-9 and 11-14 stand rejected under 35 U.S.C. § 103, as being unpatentable over the combination of Cade and Akikuni.

The examiner finds (Supplemental Answer, page 3) Akikuni teaches "a gelatin capsule containing a water-in-oil emulsion[ ]of perilla oil, perilla extract, polyglycerol fatty acid ester, and monoglycerol fatty acid ester." In addition, the examiner finds (id.) Akikuni teaches "that fats and oils, which contain omega-2-polyenoic fatty acid (polyunsaturated fatty acids), and perilla treat inflammatory bowel disease (IBD)." According to the examiner (id.), since Akikuni "does not specify the composition of the gelatin capsule," Cade is relied upon "to teach a xylose hardened gelatin capsule." In this regard, the examiner finds (Supplemental Answer, bridging paragraph, pages 3-4), Cade teaches "a hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation." According to the examiner (Supplemental Answer, page 4), Cade teaches that additives such as xylose were added to the gelatin solution "to reduce water permeability and hygroscopicity. . . ." In this regard, the examiner finds (id.), "Cade teaches capsules with low permeability to water vapor[,] reduce sensitivity to storage conditions and improve the protection of the compositions contained within . . . since permeation by the environment may cause the composition within to agglomerate or degrade chemically . . . ." "It is the examiner's position that the prevention of the chemical degradation of the

capsule fill taught by Cade . . . would read on applicant's recitation of inhibiting peroxidation of the fatty acids since Cade . . . teach[es] the use of sugar additives, i.e. xylose, to prevent permeation of the environment into the capsule." Supplemental Answer, page 5.

Accordingly, the examiner finds (Supplemental Answer, page 4) a person of ordinary skill in the art at the time appellant's invention was made would have been motivated to harden the gelatin capsule taught by Akikuni with xylose as taught by Cade to prevent the degradation of the polyunsaturated fatty acids contained therein. In the alternative, the examiner finds (Supplemental Answer, bridging paragraph, pages 4-5), it would have been prima facie obvious to a person of ordinary skill in the art at the time appellant's invention was made to use the xylose hardened gelatin capsules taught by Cade to encapsulate polyunsaturated fatty acids for use in treating inflammatory bowel disease. In this regard, the examiner finds (Supplemental Answer, page 5), Cade teaches "the use of the xylose hardened gelatin capsules as a container for nutrients, medicaments, and materials that are hygroscopic."

Upon consideration of the prior art, we agree with the examiner that Akikuni teaches water-in-oil formulations. Supplemental Answer, page 3. Stated differently the formulations of Akikuni are liquid, and are incorporated into soft gel capsules. See e.g., Akikuni, Working Example 1. Akikuni teaches nothing with regard to inhibiting peroxidation of polyunsaturated fatty acids. Cade "is concerned with hard gelatin capsules with a low permeability to water

vapour. . . ." Cade, page 1. While Cade does mention that encapsulated formulations are subject to chemical degradation, Cade makes this statement with regard to "powder fills". See e.g., Cade, page 2, "[m]oisture take-up by fills from capsules or more frequently from the environment by permeation may affect the properties of powder fills: they may agglomerate or, more seriously, degrade chemically for example by hydrolysis."

With respect to either alternative presented by the examiner, we find no reason for a person of ordinary skill in the art to look to Cade to encapsulate the liquid formulations of Akikuni, much less to achieve appellant's claimed invention of inhibiting peroxidation of polyunsaturated fatty acids by encapsulating a polyunsaturated fatty acid in a xylose-hardened gelatine capsule.

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. . . . Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."
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> Most if not all inventions arise from a combination of old elements. . . . Thus, every element of a claimed invention may often be found in the prior art. . . . However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. . . . Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [Citations omitted].

In other words, "there still must be evidence that 'a skilled artisan, . . . with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000). At best, the statement of the rejection establishes that individual parts of the claimed invention were known in the prior art. We find nothing, however, to motivate a person of ordinary skill in the art to step away from the soft-gel encapsulated liquid formulations taught by Akikuni to encapsulate Akikuni's liquid formulation into a xylose-hardened gelatine capsule as taught by Cade.

On reflection, we find that the examiner failed to provide the evidence necessary to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 1-9 and 11-14 under 35 U.S.C. § 103, as being unpatentable over the combination of Cade and Akikuni

The combination of Yajima and Cade:

Claims 1-5, 7, and 9-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Yajima and Cade.

The examiner finds (Supplemental Answer, page 11), "Yajima teaches the prevention of oxidation of oils and fats, and soft gelatin capsules contining the fats and oils." In this regard, the examiner finds (id.), Yajima teaches "that the prevention of the oxidation of oils and fats is accomplished by physical means

such as keeping oils and fats away from oxygen, storing them at low temperatures, and adding antioxidants."

According to the examiner (id.), since Yajima "does not specify the composition of the gelatin capsule," Cade is relied upon to teach a xylose hardened gelatin capsule "with reduced water transport or water vapor permeation. . ." In this regard, the examiner finds (Supplemental Answer, pages 11-12), "Cade teaches capsules with low permeability to water vapor[,] reduce sensitivity to storage conditions and improve the protection of the compositions contained within . . . since permeation by the environment may cause the composition within to agglomerate or degrade chemically . . . ." "It is the examiner's position that the prevention of the chemical degradation of the capsule fill taught by Cade . . . would read on applicant's recitation of inhibiting peroxidation of the fatty acids since Cade . . . teach[es] the use of sugar additives, i.e., xylose, to prevent permeation of the environment into the capsule." Supplemental Answer, bridging paragraph, pages 11-12.

Accordingly, the examiner finds (Supplemental Answer, page 12) a person of ordinary skill in the art at the time appellant's invention was made would have been motivated to harden the gelatin capsule taught by Yajima with xylose as taught by Cade to prevent the degradation of the polyunsaturated fatty acids contained therein. In the alternative, the examiner finds (id.) it would have been prima facie obvious to a person of ordinary skill in the art at the time appellant's invention was made to use the xylose hardened gelatin capsules

taught by Cade to encapsulate polyunsaturated fatty acids "to prevent thrombi and for their nutritional value" as taught by Yajima.

However, as appellant points out (Brief, page 10), "Yajima teaches the reduction of oxidation of oils and fats by the use of chemical antioxidant preservatives mixed into the oil and fat composition contained within a soft gelatin capsule." Yajima does not teach or suggest the use of a hardened capsule, and Cade does not teach or suggest inhibiting peroxidation of polyunsaturated fatty acids.

Therefore, for the reasons set forth above with regard to the combination of Yajimai and Cade, we agree with appellant (Brief, page 10), "[o]ne of ordinary skill in the art viewing Yajima and Cade would not be motivated to use the capsule of Cade with the composition of Yajima for the purpose of oxidative prevention. . . ." As appellant points out (Brief, page 11), "the teaching in Cade of chemical degradation is limited to degradation caused by moisture. Cade does not disclose or suggest any inhibition of peroxidation."

On reflection, we find that the examiner failed to provide the evidence necessary to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 1-5, 7, and 9-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Yajima and Cade.

The combination of Fischer and Buser:

Claims 1-5, 7, and 9-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Flacher and Buser. Appellant has

separately argued claims 6 and 7. Reply Brief, page 4. These claims, however, are not rejected under the combination of Fischer and Buser. Appellant has not separately argued any claim that is rejected under this combination of references, accordingly claims 1-5 and 12-14 will stand or fall together. Since the claims stand or fall together, we limit our discussion to representative independent claim 1. Claims 2-5 and 12-14 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Supplemental Answer, page 20), Fischer "teaches a gelatin capsule with controlled active release and the process for producing the gelatin capsule." In this regard, the examiner finds (id.) Fischer "recognizes that it is desirable that many pharmaceutical actives release at a specific time or until they have reached the small intestine." To do this, the examiner finds (id.), Fischer "teaches a method of hardening gelatin capsules with . . . xylose. . . ." The examiner recognizes, however, that Fischer does not teach a xylose hardened gelatin capsule that contains polyunsaturated fatty acids.

The examiner relies on Buser to make up for the deficiency in Fischer. According to the examiner (id.), Buser "teach[es] the treatment of inflammatory bowel diseases using an oral dosage form containing omega-3-polyunsaturated fatty acids." In this regard, the examiner finds (Supplemental Answer, bridging paragraph, pages 20-21) Buser "found that the optimum combination of absorption and the absence of side effects occur if the release of the

polyunsaturated fatty acids is controlled to occur in the ileum." To do this Buser teaches column 3, lines 50-55,

> [t]he coating must be such as to release the acid in the ileum, preferably in the mid-ileum. Usually, dissolution of the coating will be entirely time dependent but a coating relying on a combination of time and pH dependence can be used. Suitably, the coating is resistant for a period of 30 to 60 minutes at pH 5.5.

Based on this evidence, the examiner finds (Supplemental Answer, page 21) it would have been prima facie obvious to a person of ordinary skill in the art to incorporate the polyunsaturated fatty acids of Buser into the xylose hardened gelatin capsules taught by Fischer, for use in the treatment of inflammatory bowel disease. According to the examiner (id.), since Fischer "teaches an improved controlled release capsule that is simple, cost-effective, and environmentally and physiologically safe over the prior art controlled release gelatin capsules," a person of ordinary skill in the art would have been motivated to incorporate the polyunsaturated fatty acids taught by Buser into the xylose hardened gelatin capsules of Fischer. We find no error in the examiner's prima facie case of obviousness.

In response, appellant asserts (Reply Brief, page 3) Fischer "discloses gelatin capsules but does not discuss polyunsaturated fatty acids or the peroxidation of polyunsaturated fatty acids. Fischer is silent as to peroxidation in general. Buser teaches polyunsaturated acids and a problem of oxidation of the polyunsaturated acids, but solves the problem using chemical antioxidants." Therefore, appellant concludes that the prior art does not reach the requirement

of appellant's claimed invention that the gelatin capsule is "xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids." Id. We are not persuaded by appellant's argument. The discovery that a claimed composition possesses a property not disclosed for the prior art subject matter, does not by itself defeat a prima facie case. In re Shetty, 566 F.2d 81, 86, 195 USPQ 753, 756 (CCPA 1977).

Appellant fails to direct our attention to any evidence on this record, and we find none, that would suggest that the xylose-hardened capsules as taught by Fischer would not inhibit peroxidation of polyunsaturated fatty acids contained therein. Further to the extent that appellant asserts that Buser incorporate antioxidants into their polyunsaturated fatty acids, we note that appellant's claim 1 does not exclude the presence of an antioxidant in addition to the polyunsaturated fatty acid.

Of reflection, we find no error in the rejection of claim 1 under 35 U.S.C. § 103 as being unpatentable over the combination of Fischer and Buser. Accordingly, the rejection is affirmed. As discussed supra claims 2-5 and 12-14 fall together with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

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